

QA: QA

**U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT OQA-ARC-01-15
OF THE
OFFICE OF QUALITY ASSURANCE
AT
LAS VEGAS, NEVADA
SEPTEMBER 24 –28, 2001**

Prepared by: _____
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Date: _____

Approved by: _____
James Blaylock
Office of Quality Assurance

Date: _____

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) audit OQA-ARC-01-15, the audit team determined, except those areas where conditions adverse to quality (CAQ) were identified, the Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance (OQA) in Las Vegas, Nevada, is satisfactorily implementing the OCRWM QA Program in accordance with the U. S. Department of Energy (DOE) OCRWM DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD), and implementing procedures.

QA Program Sections 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, and 18.0 were determined to be effectively implemented, based on the activities evaluated during the audit. The effectiveness of implementation of QA Program Subsection 2.2.12, "Personnel Qualification" was determined to be compromised by a failure to fully implement procedures.

QA Program Sections 3.0, 8.0 through 15.0, Supplements I through V, and Appendix A, B and C were not within the scope of this audit.

The audit team identified four CAQ during the audit. Two resulted in the issuance of Deficiency Reports (DR) OQA-01-D-146 and OQA-01-D-147 and two were considered isolated and were corrected during the audit (CDA).

DR OQA-01-D-146 addresses that training requirements were not retrievable and the training organization does not reflect the current status of training for OQA.

DR OQA-01-D-147 addresses the failure to complete DR/Corrective Action Report form block 9.

CDA 1 addresses the failure to list all organization that a procedure applies to in Section 2.0, "Applicability." Procedure LP-4.1Q, Revision 1, ICN I, *Procurement Actions*, did not correctly reflect that the procedure applied to OQA.

CDA 2 addresses the failure to obtain a concurrence signature for voiding a DR. DR LVMO-01-D-027 was voided with only the initials of the originator to indicate concurrence with the justification for voiding the DR.

The audit team evaluated the effectiveness of corrective actions for a DR previously issued. DR OQA-01-D-002, identified in Fiscal Year 2000 (FY 00) OQA internal audit OQA-ARC-00-20, addressed the failure to list the revision of the cited requirements documents in DRs. A random sample of DRs issued since the implementation of corrective action found the corrective action to be effective.

2.0 SCOPE

A compliance-based audit was conducted to evaluate the implementation of the QA program to determine whether it meets the requirements and commitments imposed by the OCRWM. This was done by verifying implementation, adequacy, and determining the effectiveness of the QA program in place, as well as verifying compliance with requirements. In addition, a review of the status of a past OCRWM deficiency document identified during the FY 00 QA internal audit of the OQA was included in the scope of this audit to determine the effectiveness of corrective actions.

The audit team reviewed the status of open and closed deficiency documents that were generated during the previous OQA audit to determine the effectiveness of in-process and completed corrective actions by OQA.

In accordance with the approved audit plan, the following QA Program Sections were evaluated:

Section 1	Organization
Section 2	Quality Assurance Program
Section 4	Procurement Document Control
Section 5	Implementing Documents
Section 6	Document Control
Section 7	Control of Purchased Items and Services
Section 16	Corrective Action
Section 17	Quality Assurance Records
Section 18	Audits

As stated in the approved audit plan, audit OQA-ARC-01-15 was a limited scope audit. The following QA Program Sections were not evaluated as a part of this audit:

Section 3.0	Design Control
Section 8.0	Identification and Control of Items
Section 9.0	Control of Special Processes
Section 10.0	Inspection
Section 11.0	Test Control
Section 12.0	Control of Measuring and Test Equipment
Section 13.0	Handling, Storage, and Shipping
Section 14.0	Inspection, Test, and Operating Status
Section 15.0	Nonconformances
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement IV	Field Surveying
Supplement V	Control of the Electronic Management of Data
Appendix A	High-Level Waste From Production
Appendix B	Storage and Transportation
Appendix C	Monitored Geologic Repository

3.0 AUDIT TEAM MEMBERS

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Section</u>
Robert W. Hendrickson, Audit Team Leader, National Spent Nuclear Fuel Program (NSNFP)/QA	4.0, 7.0, 16.0, 18.0
Tom L. Morgan, Auditor, NSNFP/QA	1.0, 2.0, 5.0, 6.0, 17.0

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at OQA September 24, 2001. Daily briefings were held to apprise OQA management and staff of the progress of the audit and identify any conditions adverse to quality. A post-audit meeting was conducted at the OQA on September 28, 2001. Personnel contacted during the audit, including those who attended the pre-audit conference and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that overall the QA Program is adequate and is being effectively implemented by OQA, except for QA Program Subsection 2.2.12, which was compromised by a failure to fully implement procedures. The results for each QA program section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions as a result of the audit.

5.3 Audit Activities

Attachment 2, "Summary Table of Audit Results," provides results for each QA Program Section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklists. The checklists are maintained as QA records in accordance with the directions of QAP 18.2, Revision 8, *Internal Audits*.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Conditions Adverse to Quality

Four CAQ were identified during the conduct of this audit. Two of the conditions adverse to quality are documented as DRs, and two were identified and corrected during the audit prior to the post-audit meeting. The conditions adverse to quality were evaluated against the criteria for significance and were not found to be significant conditions adverse to quality. No Deficiency Identification and Referral reports were issued as a result of the identified CAQ.

Details of the DRs are provided in paragraph 5.5.1, and CDAs are in paragraph 5.5.2.

5.5.1 Deficiency Reports (DR)

OQA-01-D-146

QARD, Revision 10, Subsection 2.2.13, “Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing” states, “Personnel who perform inspection, nondestructive examination, testing, and auditing shall be qualified in accordance with the requirements of the applicable QARD section covering the activity and QARD Subsection 2.2.12. Subsection 17.2.1 “Classifying Quality Assurance Records” requires personnel training and qualification documents be maintained as lifetime quality records.

AP-2.1Q, Revision 2, ICN 0, *Indoctrination and Training of Personnel*, Section 5.2, “Training Requirements Documentation,” requires that the manager ensure that indoctrination and training requirements, including those indoctrination and training requirements for Environmental, Safety & Health and work subject to the QARD as determined in Subsection 5.1 of AP 2.1Q are documented for each Employee or the Employee’s job function. Document training requirements on an Individual Development Plan (IDP) (for DOE personnel) or on a matrix (for contractor personnel) that indicates Training Requirements against job functions, or employee. AP-2.1Q further requires that the completed IDP and/or matrix be submitted to the Training Organization (TO). The TO is required to enter this information into their training database and forward all documents to record storage.

Contrary to the above, complete individual training requirements and history were not retrievable from record storage and the training organization does not reflect the status of training for OQA.

1. Individual training requirements could not be determined for five personnel in OQA (DOE personnel).

2. DOE IDPs have not been submitted to the TO.
3. Current training matrices could not be retrieved from the Records Processing Center or the TO for three (of three sampled) OQA (Navarro) personnel.
4. The TO records do not show completion of required training for three (of three sampled) OQA (Navarro) personnel as follows:

QAS 1 (3590)

- Working File showed training matrix requirements for Manager should have been for a QAS
- TO showed two classes as having expired and retraining required.
- TO did not show two classes as being required that management had indicated as being required for initial job qualification.
- Records storage only showed a few completed classes, no matrix on file.

QAS 2 (2526)

- TO showed two classes as having expired and retraining required.
- TO did not show six classes as being required that management had indicated as being required for initial job qualification.
- TO showed one job function related/QA training requirement class as not having been completed
- Records storage only showed a few completed classes, no matrix on file.

QAS 3 (6989)

- TO showed one classes as having expired and retraining required.
- TO did not show fourteen classes as being required that management had indicated as being required for initial job qualification.
- TO showed three job function related/QA training requirement class as not having been completed
- Records storage only showed a few completed classes, no matrix on file.

OQA-01-D-147

AP-16.1Q, Revision 4, ICN 1, *Management of Conditions Adverse to Quality*, paragraph 5.2.4.e states: “Identify the results of the Stop Work evaluation in block 9.” Attachment 4 of the procedure titled “Instructions For Completing The Office Of civilian Radioactive Waste Management Deficiency/Corrective Action Report” states in step 9: “Check ‘Yes’ or ‘No’ as applicable indicating whether a stop work condition exists.”

Contrary to these requirements, Deficiency/Corrective Action Report form block 9 is not filled in for the following deficiency reports:

BSC-01-D-071
OQA—01-D-001
BSC-01-D-082
USSGS-01-D-004

5.5.2 Deficiencies Corrected During the Audit (CDA)

The following CDAs were identified and corrected during the audit:

1. Section 2.0, “Applicability” of LP-4.1Q did not correctly reflect all organizations the procedure applied to. The procedure was revised during the conduct of the audit to correct Section 2.0. AP-5.1Q, Rev. 2, ICN 0, *Plan and Procedure, Preparation, Review, and Approval*, paragraph 5.2.3.a.3 directs the content and format comply with Attachment 6, “Content of Procedures.”
2. DR LVMO-01-D-027 was voided. Initials represented the required concurrence signature of the originator. A supplemental record has been generated with a concurrence signature. AP-16.1Q, paragraph 5.2.4.c.1 requires the initiators dated concurrence signature.

5.5.3 Follow-up of Previously Issued Deficiency Documents

OQA-01-D-002

DR OQA-01-D-002 addressed a failure to list document revision numbers of controlling documents listed as requirements violated on DRs, per the requirements of AP-16.1Q, Attachment 4. As a part of this audit, DRs closed during the last year were sampled to verify that corrective action was effective in preventing the recurrence of the listed deficiency. As a result of the review, corrective action for the subject DR was found to be effective.

6.0 RECOMMENDATIONS

There are no recommendations for this audit.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Summary Table of Audit Results

Attachment 3: Acronyms/Abbreviations

ATTACHMENT 1

Personnel Contacted During the Audit

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Drummond, Christine	BSCTraining		X	
Ferreiro, Gloria	BSCTraining		X	
Auer, Pat	NQS		X	
Barish, Vic	NQS	X		
Flaherty, James	NQS		X	
Glasser, Bill	NQS	X	X	X
Hasson, Bob	NQS	X	X	X
Hodges, Kristi	NQS	X		
Kettell, Dick	NQS		X	
Schmit, Jim	NQS	X		
Wagner, Les	NQS	X	X	X
Blaylock, James	OQA	X	X	X
Davis, R. D.	OQA	X	X	X
Murthy, Ram	OQA	X	X	X
Payne, Chris	OQA		X	
Williams, AL	OQA			X

ATTACHMENT 2

Summary Table of Audit Results

QA Element	Implementing Document	Checklist Pages	Deficiencies	Program Adequacy	Procedure Compliance	Overall
1.0	LP-1.0Q-OCRWM, Rev. 0, ICN 0	1&2		SAT	SAT	SAT
2.0	AP-2.1Q, Rev. 1, ICN 0 AP-2.2Q, Rev. 1, ICN 0 LP-2.2Q-OCRWM, Rev. 0, ICN 0 LP-2.4Q-OCRWM, Rev. 0, ICN 0 QAP 2.8, Rev. 2, BSCN 1	3-8	OQA-01-D-146	SAT	UNSAT SAT SAT SAT SAT	SAT
4.0	LP-4.1Q-OCRWM, Rev. 1, ICN 0 LP-4.2Q-OCRWM, Rev. 0, ICN 0 LP-16.1Q-OCRWM, Rev. 0, ICN 0, BSCN 1	9-17		SAT	SAT SAT SAT	SAT
5.0	AP-5.1Q, Rev. 2, ICN 0	25	CDA-1	SAT	SAT	SAT
6.0	AP-6.28Q, Rev. 0, ICN 0, BSCN 1	18&19		SAT	SAT	SAT
7.0	AP-7.4Q, Rev. 4, ICN 0	20-24		SAT	SAT	SAT
16.0	AP-16.1Q, Rev. 4, ICN 1 AP-16.3Q, Rev. 2, ICN 0	26-40	OQA-01-D-147 CDA-2	SAT	UNSAT SAT	SAT
17.0	AP-17.1Q, Rev. 2, ICN 1	41&42		SAT	SAT	SAT
18.0	QAP 18.1, Rev. 6 QAP 18.2, Rev. 8 AP 18.2Q, Rev. 0, ICN 0	43-55		SAT	SAT SAT SAT	SAT
TOTALS		55 Pages	2 DRs 2 CDAs	SATISFACTORY		

ATTACHMENT 3

Acronyms/Abbreviations

BSC	Bechtel SAIC Company, LLC
CAQ	Condition Adverse to Quality
CDA	Corrected During the Audit
DOE	Department of Energy
DR	Deficiency Report
IDP	Individual Development Plan
NQS	Navarro Quality Services
NSNFP	National Spent Nuclear Fuel Program
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
QAS	Quality Assurance Specialist
TO	Training Organization